30

What is claimed is:

July AD S

- 1. An optically pure enantiomeric compound comprising a Na⁺, Mg²⁺, Li⁺, K⁺, Ca²⁺ or N⁺(R)₄ salt of (+)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]- \underline{H} -benzimidazole or (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]- \underline{H} -benzimidazole, wherein R is an alkyl with 1-4 carbon atoms.
- 2. The optically pure enantiomeric compound according to claim 1 selected from the group consisting of (+)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1<u>H</u>-benzimidazole sodium salt, (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1<u>H</u>-benzimidazole sodium salt, (+)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1<u>H</u>-benzimidazole magnesium salt, (+)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1<u>H</u>-benzimidazole calcium salt and (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1<u>H</u>-benzimidazole calcium salt.
- The optically pure enantioneric compound according to claim 1 selected from the group consisting of (+)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole sodium salt, (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole sodium salt, (+)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole magnesium salt.
 - 4. The optically pure enantiomeric compound according to claim 1 selected from the group consisting of (+)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]-sulfinyl-1<u>H</u>-benzimidazole sodium salt and (-)-5-methoxy-2-[[(4-methoxy-2-

methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl-1 \underline{H} -benzimidazole sodium salt in their crystalline forms.

5. The optically pure enantiomeric compound according to claim 1 which is (+)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]-sulfinyl-1<u>H</u>-benzimidazole sodium salt in its crystalline form.

6. The optically pure enantiomeric compound according to claim 1 which is the compound (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]-sulfinyl-1<u>H</u>-benzimidazole sodium salt in its crystalline form.

7. A process for the preparation of an optically pure enantiomeric compound according to claim 1 which comprises separating from a racemic mixture a diastereomeric ester of formula IV

25

5

10

15

20

C

wherein Acyl designates a chiral acyl group such as mandeloyl, having either R or S configuration, and dissolving each of the separated R or S diastereomers is solved in an alkaline solution whereby the acyloxymethyl is hydrolyzed to give the optically pure enantiomeric compound.

All A3

10

15

- 8. The process according to claim 7 wherein the diastereomers are separated by chromatography or fractional crystallization.
- 9. The process according to claim 7 wherein the solvolysis is performed in alkaline solution consisting of a base in a protic solvent comprising alcohol or water; or a base in an aprotic solvent, such as dimethylsulfoxide or dimethylformamide.
- 10. The process for the preparation of a pure enantiomeric compound according to claim 7 wherein a product from the process in crystalline form is neutralized with a neutralizing agent which can be an acid or an ester, followed by treatment with a base in non-aqueous solution.
- 11. A process for the preparation of crystalline sodium salt of (+)-5-methoxy-2[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]-sulfinyl-1H-benzimidazole sodium salt or (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl] sulfinyl-1H-benzimidazole sodium salt in crystalline form which comprises neutralizing (+)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]-sulfinyl-1H-benzimidazole sodium salt crude product, respectively, is neutralized and treating said crude product with NaOH in a non-aqueous medium.
- 12. A process for the preparation of (+)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-30 2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole or (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-3)]sulfinyl]-1H-benzimidazole or (-)-5-methoxy-3-[[(4-methoxy-3,5-dimethyl-3)]sulfinyl]-1H-benzimidazole or (-)-5-methoxy-3-[[(4-methoxy-3,5-dimethy

5

10

15

20

25

30

3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1<u>H</u>-benzimidazole which comprises separating a diastereomeric ester of formula IV

$$H_3C$$
 CH_3
 CH_2
 CH_2

wherein Acyl designates a chiral acyl group such as mandeloyl, having either R or S configuration is and dissolving each of the separated diastereomers in an alkaline solution where the acyloxymethyl group is hydrolyzed off to give the optically pure enantiomeric compound after neutralization with a neutralizing agent which can be an acid or an ester.

- 13. The process according to claim 12 wherein the diastereomers are separated by chromatography or fractional crystallization.
- 14. The process according to claim 12 wherein the solvolysis is performed in alkaline solution consisting of a base in a protic solvent or of a base in an aprotic solvent.
- 15. The process according to claims 12 or 14 wherein the aprotic solvent comprises alcohol or water.
- 16. The process according to claims 12 or 14 wherein the aprotic solvent comprises dimethylsulforide or dimethylformamide.

- 17. The compound (+)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2pyridinyl)methyl]-sulfinyl]-1H-benzimidazole obtained by the process defined in claim 12.
- 18. The compound (-)-5-methoxy-2/-[[(4-methoxy-3,5-dimethyl-2-5 pyridinyl)methyl]-sulfinyl]-1H-benzimidazole obtained by the process defined in claim 12.
 - 19. A pharmaceutical composition comprising an optically pure enantiomeric compound according to the claims 1/as active ingredient and a pharmaceutically acceptable carrier.
 - 20. An optically pure enantiomeric compound or salt thereof according to claims 1 or 2 for use in therapy.
 - 21. A method for inhibiting gastric acid secretion comprising administration to a mammal including man in need of such treatment an effective amount of an optically pure compound according to claim 1.
- 22. A method for the treatment of gastrointestinal inflammatory diseases 20 comprising administration to a mammal including man in need of such treatment an effective amount of an optically pure compound or salt thereof according to claims 1 or 2.
- 23. The compound 6-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)-methyl]-25 1-[mandeloyloxymethyl]-114 benzimidazole.
 - 24. The optically pure enantiomeric compound according to claim 1 consisting of (+)-5-methoxy-2-[[(4- $\frac{1}{2}$ nethoxy-3,5-dimethyl-2-pyridinyl)methyl]-sulfinyl]-1 \underline{H} -
- benzimidazole magnesium salt in its crystalline form. 30

15

20

30

- 25. The optically pure enantiomeric compound of claim 1 consisting of (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1<u>H</u>-benzimidazole magnesium salt in its crystalline form.
- 5 26. The method of claim 21 wherein the optically pure enantiomeric compound is selected from the group consisting of (+)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1<u>H</u>-benzimidazole sodium salt, (-)-5-methoxy-2-[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1<u>H</u>-benzimidazole sodium salt, (+)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1<u>H</u>-benzimidazole magnesium salt.
 - 27. The method of claim 21 wherein the selected optically pure enantiomeric compound is in crystalline form.
 - 28. The method according to claim 22, wherein the optically pure enantiomeric compound is selected from the group consisting of (+)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1<u>H</u>-benzimidazole sodium salt, (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1<u>H</u>-benzimidazole sodium salt, (+)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1<u>H</u>-benzimidazole magnesium salt and (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1<u>H</u>-benzimidazole magnesium salt.
- 25. The method according to claim 22 or claim 28 wherein the selected optically pure enantiomeric compound is in crystalline form.
 - 30. An optically pure enantiomeric salt compound comprising the R or S diastereomeric structure of formula Ia, Ib, IIa or IIb, produced from a diastereomeric ester of formula IV, one diastereomer having been separated from

the other, dissolved in an alkaline solution and hydrolyzed therein resulting in the optically pure compound.

- 31. The compound according to claim 30 wherein one diastereomeric form is separated from the other by chromatography or fractional crystallization.
- 32. A nonaqueous process for preparing a crystalline form of an optically pure enantiomer of omeprazole magnesium salt which comprises stirring a crude preparation of the omeprazole enantiomer under nitrogen into a methanolic magnesium methoxide solution; precipitating any inorganic magnesium salts with a small addition of water; removing any precipitated inorganic magnesium salts; concentrating the residual methanolic solution; precipitating the omeprazole enantiomer by adding acetone; and filtering off the optically pure enantiomer crystals of magnesium omeprazole.
 - 33. The process of claim 32 wherein the optically pure enantiomer is (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)-methyl]sulfinyl]-1<u>H</u>-benzimidazole magnesium salt or (+)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)-methyl]sulfinyl]-1<u>H</u>-benzimidazole magnesium crystal salt.
 - 34. The process according to claim 7 or 12, wherein the chiral acyl group is mandeloyl.

20

15

5